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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/658,736

09/09/2003

Alan Shluzas

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09/19/2006

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

WOODALL, NICHOLAS W

ART UNIT

PAPER NUMBER

3733

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/658,736

Applicant(s)

SHLUZAS ET AL.

Examiner

Nicholas Woodall

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20, 22-25, and 27 is/are rejected.
- 7) ☒ Claim(s) 21 and 26 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>08/20/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 08/20/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. The examiner has not received any of the foreign patent documents or non-patent literature documents listed on the information disclosure statement.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Foley (U.S. Patent 5,792,044) in view of Davison (U.S. Patent 6,187,000).

Regarding claim 1, Foley discloses a method of treating the spine that is applicable to a wide range of surgical procedures in any region of the body via any approach (column 9 lines 63-67 and column 10 lines 1-11). Foley discloses the method comprising the steps of implanting a fusion device in the space between at least two vertebrae and inserting an access device into the patient (column 15 lines 35-67 and column 16 lines 1-9). Foley further discloses that fixation and fusion methods can be

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performed through the access device. The fusion method Foley discloses further includes delivering bone graft substances to the vertebra through the access device prior to performing a decompression method and inserting the implant into the spinal disk space (column 16 lines 1-9). Foley fails to disclose the access device having a distal end that is actuated to extend over the vertebrae. Davison teaches of an access device that may be used in a surgical procedure in any region of the body and has a distal end that is capable of being expanded after being inserted into the patient in order to provide a substantially larger working area for the surgeon inside the body (column 4 lines 40-43). It would have been obvious to one having ordinary skill in the art at the time of the invention to perform the method of Foley with an access device having an expandable distal end in view of Davison in order to provide a substantially larger working area for the surgeon inside the body.

The combination of Foley and Davison discloses the invention as claimed except for the device extending across at least a portion of each of the three adjacent vertebrae after actuating the distal portion of the access device. The necessary size of the access device is relative to the size of the patient and the area of the body the procedure is being performed. If the access device is used in the lumbar region of the spine it would cover less vertebrae than if it were used in the cervical area in the spine. Also if the same sized device were used on a child it would cover more vertebrae than if it were used in the same region of the spine on an adult. It would have been an obvious matter of design choice to make the access device be able to extend over at least a portion of each of the three adjacent vertebrae after actuating the distal portion, since such a

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modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

4. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley (U.S. Patent 5,792,044) in view of Davison (U.S. Patent 6,187,000) further in view of Justis (U.S. Patent 6,293,949).

Regarding claims 1-7, the combination of Foley and Davison discloses the invention as claimed except for performing a multi-level procedure through the access device across the at least three vertebrae (claim 1). Justis discloses a method for fixing and fusing the vertebrae of a spine across at least two adjacent vertebrae in order to stabilize a portion of the spinal column (column 4 lines 31-57). It would have been obvious to one having ordinary skill in the art at the time of the invention to perform the method of Foley as modified by Davison with method of fixing a spine using a multi-level stabilization system in view of Justis in order to stabilize a portion of the spinal column.

5. Claims 1, 6, 9, 11, 12, 18, 19, 20, 23, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley (U.S. Patent 5,792,044) in view of Davison (U.S. Patent 6,187,000) further in view of Justis (U.S. Patent 6,293,949) further in view of Mathews (U.S. Patent 6,793,656).

Regarding claims 1, 6, 9, 11, 12, 18, 19, 20, 23, 24, and 25 the combination of Foley, Davison, and Justis discloses the invention as claimed except for the method further comprising performing decompression through the access device prior to performing fixation. Mathews discloses a method for fixing and fusing the vertebrae of

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the spine comprising the step of performing decompression prior to performing the fixation procedure in order to remove tissue from the spine (column lines 33-65). It would have been obvious to one having ordinary skill in the art at the time of the invention to perform the method of Foley as modified by Davison as further modified by Justis with the step of performing a decompression prior to performing fixation in order to remove tissue from the spine.

6. Claims 22 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley (U.S. Patent 5,792,044) in view of Davison (U.S. Patent 6,187,000) further in view of Justis (U.S. Patent 6,293,949) further in view of Mathews (U.S. Patent 6,793,656) further in view of Chan (U.S. Patent 6,626,909).

Regarding claims 22 and 27, the combination of Foley, Davison, Justis, and Mathews discloses the invention as claimed except for the portion of bone removed comes from the lamina. Chan teaches the method for the fixation and fusing of the spine. The method includes performing a laminectomy prior to attaching the elements of the fixation system to the vertebrae (Figure 11) in order to decompress the vertebrae. It would have been obvious to one having ordinary skill in the art at the time of the invention to perform the method of Foley as modified by Davison as modified by Justis as further modified by Mathews with the step of performing a laminectomy prior to the attaching the elements of the fixation system in order to decompress the vertebrae.

7. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley (U.S. Patent 5,792,044) in view of Davison (U.S. Patent 6,187,000).

Foley discloses a method of treating the spine that is applicable to a wide range of surgical procedures in any region of the body via any approach including an anterior approach (column 9 lines 63-67 and column 10 lines 1-11). The method comprises the steps of inserting an access device into the patient through an incision to expose the vertebrae and the step of positioning bone graft substances across the posterior aspects of the spine through the access device. Foley further discloses that both fixation and fusion procedures can be performed through the access device. Foley fails to disclose the step of actuating the access device to expand the distal portion across the exposed vertebrae. Davison teaches a method for using an access device comprising the step of actuating the access device to expand the distal portion across the exposed vertebrae in order to provide a substantially larger working area for the surgeon inside the body (column 4 lines 40-43). It would have been obvious to one having ordinary skill in the art at the time of the invention to perform the method of Foley with an access device having an expandable distal end in view of Davison in order to provide a substantially larger working area for the surgeon inside the body.

The combination of Foley and Davison discloses the invention as claimed except for the device extending across at least a portion of each of the three adjacent vertebrae after actuating the distal portion of the access device. The necessary size of the access device is relative to the size of the patient and the area of the body the procedure is being performed. If the access device is used in the lumbar region of the spine it would cover less vertebrae than if it were used in the cervical area in the spine. Also if the same sized device were used on a child it would cover more vertebrae than if it were

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used in the same region of the spine on an adult. It would have been an obvious matter of design choice to make the access device be able to extend over at least a portion of each of the three adjacent vertebrae after actuating the distal portion, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

8. Claims 14, 15, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley (U.S. Patent 5,792,044) in view of Davison (U.S. Patent 6,187,000) further in view of Mathews (U.S. Patent 6,793,656).

Regarding claims 14, 15, and 17, the combination of Foley and Davison discloses the invention as claimed except for the method comprising the steps of providing fasteners through the access device for attaching to the vertebrae, attaching the fasteners to the vertebrae, inserting an elongated member through the access device and moving the member adjacent to the fasteners, and securing the elongated element to the fasteners. Mathews teaches a method of using a spinal stabilization system across adjacent vertebrae comprising the steps attaching fasteners to the vertebrae, inserting an elongated member adjacent to the fasteners, and securing the elongated member to the fasteners (column 5 lines 14-67 and column 6 lines 1-44) in order to stabilize the spine. It would have been obvious to one having ordinary skill in the art at the time of the invention to perform the method of Foley as modified by Davison with the included steps of attaching fasteners to the vertebrae, inserting an

elongated member adjacent to the fasteners, and securing the elongated member to the fasteners in order to stabilize the spine.

9. Claims 14, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley (U.S. Patent 5,792,044) in view of Davison (U.S. Patent 6,187,000) further in view of Mathews (U.S. Patent 6,793,656) further in view of Justis (U.S. 6,293,949).

Regarding claims 15 and 16, the combination of Foley, Davison, and Mathews discloses the invention as claimed except for the step of providing a fastener through the access device for a third vertebrae and attaching the elongated member to a third fastener. Justis teaches a spinal stabilization system for use over multiple vertebrae (column 4 lines 31-36). Justis further teaches a method for using a spinal stabilization system comprising the steps of providing fasteners for multiple vertebrae, attaching the fasteners to the multiple vertebrae, and to place an elongated element adjacent to the fasteners (column 4 lines 58-67 and column 5 lines 1-25) in order to stabilize a plurality of vertebrae. It would have been obvious to one having ordinary skill in the art at the time of the invention to perform the method of Foley modified by Davison further modified by Mathews with the steps of providing fasteners for multiple vertebrae, attaching the fasteners to the multiple vertebrae, and to place an elongated element adjacent to the fasteners in order to stabilize a plurality of vertebrae.

Allowable Subject Matter

10. Claims 21 and 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited art the examiner felt was relevant to the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is 571-272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

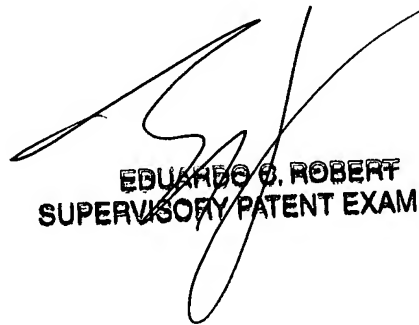
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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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EDUARDO S. ROBERT
SUPERVISORY PATENT EXAMINER